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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

THE VACCINE CENTER LLC, d/b/a THE VACCINE CENTER AND TRAVEL MEDICINE CLINIC, a Nevada limited liability company,

Plaintiff.

- vs. -

GLAXOSMITHKLINE LLC, a Delaware limited liability company; APEXUS, INC., a Delaware corporation; SOUTHERN NEVADA HEALTH DISTRICT; DOES I – X and ROE CORPORATIONS I - X, inclusive,

Defendants.

Case No. 2:12-cv-01849

> REPLY TO PLAINTIFF'S RESPONSE TO APEXUS'S MOTION FOR SUMMARY **JUDGMENT**

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Local Rule 56-1, and the Scheduling Order entered June 3, 2014, Defendant Apexus, Inc. ("Apexus"), by and through its undersigned counsel, submits the following reply in further support of its Motion for Summary Judgment (Docket No. 158).

REPLY TO PLAINTIFF'S RESPONSE TO APEXUS'S MOTION FOR SUMMARY JUDGMENT DAL 79378882v4 110804.011400

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I. **SUMMARY OF THE REPLY**

A. Implied Immunity Applies to Apexus, Inc.

Plaintiff has not produced any evidence or law that indicating that Apexus, Inc. ("Apexus") is not immune from its work in negotiating prices for vaccines. At most, Plaintiff argues that because vaccines are not specifically included in the 340B Program, Apexus is not entitled to This viewpoint is skewed, especially in light of the deference HRSA is owed in interpreting the 340B enabling legislation and administering the 340B Program. HRSA signed a contract that required Apexus to include vaccines, and vaccines are not specifically excluded under the 340B legislation. As a result, Apexus is entitled to immunity based upon HRSA's interpretation of the 340B Program and the Prime Vendor Contract.

Apexus maintains clear immunity as a result of its activities incident to the administration of, and in fulfillment of its obligations under, the 340B Prime Vendor Program. The United States Department of Health and Human Services Health Resources and Services Administration ("HRSA") delegated the obligation to negotiate contracts under the 340B Program to Apexus as the 340B Prime Vendor. In its role, Apexus is an instrumentality of the federal government because it fulfills the statutory requirements of the 340B Program that requires HRSA to enter into contracts for covered drugs. Any unfair use or abuse by third parties after receipt of the price discounts afforded by the lawful and sanctioned conduct of Apexus fails to destroy the immunity afforded to Apexus as an instrumentality of the federal government.

Importantly, Plaintiff's sole allegation of a wrongful act committed by Apexus is the inclusion of negotiated prices for vaccines – an act specifically included in the scope of the value added products requested by HRSA, and one which Apexus was specifically contracted to provide. Because Apexus manages the 340B Prime Vendor Program on behalf of HRSA and the Office of Pharmacy Affairs ("OPA") and is the stand-in on behalf of HRSA and OPA, it maintains the same level of immunity that these governmental agencies maintain against antitrust liability.

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В. **Public Policy Favors Vaccination**

The importance and well-established benefits of public health programs are well documented. Plaintiff, however, desires to put its own profits above the public good by engaging in a practice which would restrict access, drive up costs of needed vaccines, and otherwise restrict inoculations to the overall community. As a practical matter, negotiating lower prices for vaccines, and making these products available as value added products under the 340B Prime Vendor Program gives access to a wider demographic that ultimately increases vaccination rates. The inclusion of negotiated vaccine pricing, therefore, serves the public interest, and the stated public health goals of HRSA.

Plaintiff requests that this Court condone restricting the much needed vaccinations offered to the underserved community to only those willing to travel to its facility, and pay a higher price. Such a result serves only Plaintiff's economic interest at the expense of public health. Reducing access to needed drugs and other key medical suppliers is not the goal of the 340B Prime Vendor Program. Plaintiff's position also defies the longstanding medical science which favors higher vaccination rates as beneficial not only to those vaccinated, but to the community as a whole.

C. Plaintiff's Cause of Action for Aiding and Abetting Is not Actionable as a Matter of Law²

In an attempt to evade Apexus's immunity for antitrust liability in complying with the Prime Vendor Contract, Plaintiff tries to hold Apexus liable for the actions of others over which Apexus had no control. However, as a matter of law, the third-party conduct alleged cannot give rise to liability to Apexus for "aiding and abetting" civil violations of the U.S. antitrust laws, and specifically the Robinson-Patman Act. Apexus is not liable under this claim because a cause of action for aiding and abetting civil violations of the U.S. antitrust laws, and specifically the Robinson-Patman Act, does not exist under federal law. To the extent that Plaintiff rests its "aiding and abetting" theory on some state law cause of action, Plaintiff's state law theory is similarly

¹ One need look no further than the Government's concerted effort to develop and implement an effective Polio vaccine

to see the demonstrated communal benefits of a vaccinated populace.

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² Plaintiff raised this issue in its Response. Apexus will address this issue in its Reply even though Apexus did not first raise the aiding and abetting issue in its Motion for Summary Judgment. 28

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unrecognized. Accordingly, even taken in the most liberal factual context, and even if this Court declines to find that Apexus is immune from suit, Plaintiff's claims as to Apexus fail.

II. APEXUS MAINTAINS IMMUNITY AS AN INSTRUMENTALITY OF THE **GOVERNMENT**

Nothing set forth in Plaintiff's response changes the fact that Apexus is entitled to conductbased immunity because it is an instrumentality of the federal government. The United States and its officials acting in their official capacities are immune from the antitrust laws. See U.S. Postal Service v. Flamingo Industries, 540 U.S. 736 (2004). Antitrust immunity also includes private entities who act as the instrumentality of a federal agency. See Champaign-Urbana News Agency v. J. L. Cummins News, 632 F.2d 680 (7th Cir. 1981); Medical Ass'n of State of Ala. v. Schweiker, 554 F.Supp. 955 (M.D.Ala. 1983) (granting motion to dismiss Sherman Act claim against private corporation, funded by the federal government under the Rural Health Initiative Program, alleging that competition from defendant as a part of the Rural Health Initiative Program was financially hurting the plaintiffs). Thus, the question for this Court is whether or not Apexus was acting as the instrumentality of a federal agency when negotiating reduced pricing for vaccines available to covered entities under the 340B Program. The clear and unrebuttable answer to this inquiry is yes.

A. The Nature of the Activity Supports Immunity

In making a determination of immunity, the court looks to the "nature of the activity." See Name. Space, Inc. v. Network Solutions, Inc., 202 F.3d 573, 580 (2nd Cir. 2000). Plaintiff centers its complaint on Apexus purportedly assisting covered entities in obtaining price discounts on vaccines. See Amended Complaint ¶ 65. As noted in Name. Space, if the conduct at issue was compelled, endorsed, or directed by the federal government via contract or otherwise, immunity applies. Id. (emphasis added). The conduct at issue in this case, the negotiation of price discounts, was the very charge to Apexus embodied in the Prime Vendor Contract governing Apexus's relationship as delegee of the federal government.

In the specific bid solicitation which ultimately became the contract binding Apexus, HRSA sought an entity able to offer "[1]ower cost products and services not included in the 340B Program

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(e.g. vaccines, etc.)." HRSA made the election to include a more expansive range of products within the purview of the overall administration of the 340B Program based upon the comments and requests of covered entities. Apexus has now merely implemented these contractual directives.

Plaintiff argues that because vaccines are not specifically <u>included</u> in the 340B Program, the inclusion of these products in the Prime Vendor Program does not provide for immunity. Plaintiff's argument is incorrect. The focus should be on whether vaccines are specifically excluded. If not, then the Court must look to see if HRSA had the power to include vaccines within the 340B Program.

An agency like HRSA is entitled to deference when it fills a gap left by Congress with regard to how to implement a statute or regulation. United States v. Mead Corporation, 121 S. Ct. 2164, 2171 (2001) (citing Chevron, Inc. v. Natural Resources Defense Council, 104 S. Ct. 2778 (1984)). "The well-reasoned views of agencies implementing a statute 'constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance." Id. (citing Bragdon v. Abbott, 118 S. Ct. 2196 (1998)). The inclusion of vaccines in the 340B program is entitled to Chevron deference. United States v. Mead Corp., 533 U.S. 218, 226-27, (2001) ("administrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority"); Barnhart v. Walton, 535 U.S. 212, 217-18 (2002).

Captain Mitchell, the head of the OPA at the time OPA and HRSA included vaccines as an example for value added products, fulfilled the mandate granted to HHS by Congress to develop and operate a 340B program by authorizing Apexus to solicit vaccines to be included in the Prime Vendor Program. Despite whatever ad hominem attack Plaintiff levies on Captain Mitchell, his authority and record are unassailable.³ He was the Director of the Office of Drug Pricing, and one

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³ As part of its manufactured attacks upon Capt. Mitchell, Plaintiff asserts on the final page of the Opposition that Apexus concealed the fact that Captain Mitchell is an independent contractor for Apexus. This is simply not true. In paragraph 3 of the very first page of Capt. Mitchell's Declaration he states: "I am currently an independent contractor, playing a leadership role in advancing medication safety initiatives within the safety-net community, under contract with Apexus". All of Plaintiff's attacks on Capt. Mitchell are equally as spurious and should be disregarded.

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Furthermore, unlike the more-narrow grants of rulemaking authority addressed in Pharmaceutical Research and Manufacturers of America v. U.S. Dept. of Health and Human Service, 313 F.3d 600 (D.C. 2014) the Secretary had broad autonomy to define the prime vendor program here, including the authority to include value-added vaccines in the bid parameters. While Pharmaceutical Research held that certain decisions were not entitled to Chevron deference, the delegated power and methodologies present here are significantly more robust. See United States v. Mead Corp., 533 U.S. 218, 226-27, (2001) ("administrative implementation of a particular statutory provision qualifies for Chevron deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority."); Barnhart v. Walton, 535 U.S. 212, 217-18 (2002) (If a statute speaks clearly to the precise question at issue, court give effect to the unambiguously expressed intent of Congress. However, if the statute is silent or ambiguous with respect to the specific issue, courts sustain the agency's interpretation if it is based on a permissible construction of the Act).

Notwithstanding the attack on Captain Mitchell, even if Health and Human Services did not have express statutory authority to include vaccines in the prime vendor program, a court should give deference to HHS' interpretive choice to do so. "[W]hether or not they enjoy any express delegation of authority on a particular question, agencies charged with applying a statute necessarily

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make all sorts of interpretive choices, and while not all of those choices bind judges to follow them, they certainly may influence courts facing questions the agencies have already answered." United States v. Mead Corp., 533 U.S. 218, 227-28 (2001). "[W]e have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." Id. (internal marks omitted). OPA's decision is entitled to deference because it is a sub agency of HHS. OPA made a choice as to how to provide much needed vaccines at a reduced cost to safety net providers and covered entities. That choice should be honored and should not subject Apexus to liability.

В. **Vaccines Are Contractually Mandated**

Plaintiff incorrectly assumes, without support in law or fact, that how the terms of the Prime Vendor Contract came into being is determinative of whether or not immunity applies. It is not. While Plaintiff goes to great lengths to characterize Apexus's value added services as some concerted money grab, and wishes to introduce parole evidence in an attempt to negate the integrated terms of Apexus's duties as the 340B Prime Vendor, Plaintiff ignores two critical factors: (1) the integrated contract between HRSA and Apexus controls the scope of the parties relationship and duties, and, (2) the sale of the listed vaccines is specifically included in the Prime Vendor Contract.

The integrated Agreement between HRSA and Apexus specifically set forth that "the 340B Prime Vendor shall in meeting the requirements of this Agreement perform the work in accordance with the proposal to the Health Resources and Services Administration dated April 16, 2009." See Agreement at p. 1. And the proposal directly responded to HRSA's request to include value added products, "e.g., vaccines." HRSA could have negated, eliminated, or otherwise excluded the vaccine inclusion within their acceptance of the proposal to the Health Resources and Services Administration dated April 16, 2009, or elected to select a different proposal. Rather, it instead specifically included and incorporated the vaccine provisions in its acceptance of Apexus's proposal. Inclusion of vaccines, and integration of Apexus's proposal into the final governing document charging Apexus as the Prime Vendor serves as an explicit direction to Apexus, and

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operates as consent of HRSA to negotiate prices for the vaccines as set forth in the proposal adopted and integrated by HRSA. See Byers v. Intuit, 600 F.3d 286 (3rd Cir. 2010). Indeed, just as in Byers, the Agreement itself mandates the allegedly unlawful act (here the negotiation of the vaccine prices). Again, just as in *Byers'* relationship with the IRS, HRSA was clearly statutorily authorized to enter into the Prime Vendor Agreement. See 42 U.S.C. § 256b. And, the provisions to which Plaintiff objects (the inclusion of vaccines) clearly was a part of the 340B Prime Vendor Contract between HRSA and Apexus.

Because of the specific timing of the 340B Prime Vendor Contract, Apexus must either breach its Contract with HRSA or comply and risk suit by plaintiffs like the Vaccine Center. Federal law does not require Apexus to make such a choice. Indeed, federal law provides Apexus with immunity so that it can act as mandated by the HRSA Contract and not have to fear being sued.

A private party acting anti-competitively pursuant to an agreement with a government agency enjoys immunity when: (1) the government agency is acting pursuant to a clearly defined policy or program; and (2) the private party is acting at the direction or consent of the government agency. See Byers v. Intuit, 600 F.3d 286 (3rd Cir. 2010). Since both Byers prongs are satisfied, this Court, like the one in Byers must conclude that Apexus is entitled to conduct-based, implied antitrust immunity with respect to the allegedly anti-competitive action taken pursuant to the Agreement between HRSA and Apexus.

To highlight the inherent contradiction in Plaintiff's attempt to destroy immunity, this Court need merely compare whether HRSA would be liable if it performed Apexus's job as prime vendor. To accept Plaintiff's position that Apexus is not immune, the court would have to assume that (1) the federal government's negotiation of prices for the listed vaccines would subject the federal government to antitrust liability (it would not), (2) the government's inclusion of vaccines in the contractual mandate to Apexus results in antitrust violations (it did not), or (3) Apexus's adherence to the contractual mandate of the federal government by negotiating prices for the listed vaccines subjects them to antitrust liability (it does not).

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Regardless of how Plaintiff wishes to characterize Apexus's conduct, or the cause of action it asserts, the "nature of the activity" leads inexorably to a single conclusion: Apexus acted as an instrumentality of the federal government via a direct and clear contractual mandate to include value added services and "[1]ower cost products and services not included in the 340B Program (e.g. vaccines, etc.)." Because the complained of conduct (the negotiation of vaccine pricing) was compelled, endorsed, or directed by the federal government via contract or otherwise, immunity applies. See Champaign-Urbana News Agency v. J. L. Cummins News, 632 F.2d 680 (7th Cir. 1981). And the inclusion of vaccines was explicitly authorized by HRSA through its contract with Apexus. See Mitchell Dec. ¶ 13.

1. The Otter Tail Exception is Inapplicable

Plaintiff urges this Court to apply only half of the two pronged Otter Tail exception, intentionally eliminating the second critical prong of the test. See Opposition at p. 17. Otter Tail held that even when the circumstances otherwise dictated that a private entity was entitled to implied antitrust immunity, such protection would not be accorded if: (1) the private entity had "insisted" on anti-competitive restrictions in its contract with a government agency; and (2) those restrictions "hindered" the government. See Otter Tail Power Co. v. United States, 410 U.S. 366, 378-79, 93 S.Ct. 1022, 35 L.Ed.2d 359 (1973)(emphasis added). Importantly, in arguing the exception, (1) Plaintiff fails to show that HRSA's inclusion of vaccines as an example of value added products was a decision forced upon HRSA or not made by HRSA independently;⁵ (2) Plaintiff fails to provide any basis that HRSA's acceptance of the Apexus proposal was anything other than of HRSA's own accord, and, (3) that any inclusion of vaccines in the proposal (if "insisted") actually hindered the government. Thus, the Complaint and Plaintiff's briefing is devoid

⁴ As noted by the Director of the Office of Pharmacy Affairs during the relevant timeframe, Captain Mitchell, the Prime Vendor was required to offer products and services that mimicked certain products and services offered by the Veterans Administration's Prime Vendor. See Mitchell Dec. ¶ 9.

⁵ Plaintiff assumes without support that a bid solicitation to numerous entities which HRSA was free to accept or reject is tantamount to "insistence" under Otter Tail. It is not.

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of any suggestion that the alleged restrictions "hindered" the government, nor is there any evidence of such a hindrance. Accordingly, just as in *Byers*, the Otter Tail exception is inapplicable.

Plaintiff likewise makes an unsubstantiated logical leap and "doomsday scenario" with respect to its claim that "Apexus could sell every possible medical product below market". See Opposition at p. 22. First, and most importantly, Apexus does not sell any medical products. Secondly, Apexus is limited to the products and services within the contract executed with HRSA, and HRSA's ability to add products to the Contract is limited to what is expressly provided for in the statutes and what can be included in light of the *Chevron* deference offered to agencies to fill gaps in enabling legislation. See supra.

Thus, the limitations placed upon Apexus are clear and deliberate. Apexus is limited to negotiating prices for those items to which it received a charge to do so. Plaintiff suggests that Apexus steamrolled HRSA into the inclusion of vaccines. An independent review committee and HRSA's Procurement Office reviewed the various proposals and selected Apexus's bid. Id. Yet Plaintiff would have this Court believe that Apexus somehow demanded the inclusion of vaccines, and was able to exert such leverage that HRSA had no choice but to acquiesce. Surely it did not, and the boldface and unsupported idea that Apexus had any ability to dictate terms to HRSA is ludicrous. Further, all available evidence contradicts this illogical assumption. See Mitchell Dec. ¶ 17.

C. Regardless of Third-Party Conduct, Apexus Maintains Immunity

Despite whatever claims Plaintiff may have with respect to the remaining Defendants as a result of their independent conduct, Apexus's actions pursuant to its participation in a lawful program cannot give rise to liability. Again, Plaintiff's complaints with respect to the sales undertaken by the remaining defendants – to whom and in what amounts, or under what authority, do not destroy Apexus's lawful administration of its duly delegated and immune actions.

⁶ The sole mention of any hindrance of the government is found in a single sentence in the Opposition at p. 26. Beyond the sole assertion that "those restrictions hindered the government" Plaintiff fails to offer any explanation, evidence, or

Apexus negotiates prices between parties but is not otherwise engaged in purchases or sales.

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Specifically, if the Court finds, as it should, that the negotiation of vaccine pricing by Apexus under the Prime Vendor Program was lawful and/or immune from liability, a co-defendants' election to engage in unlawful conduct as a result of Apexus's lawful act fails to make Apexus a conspirator to the acts about which they neither had knowledge or participation. Whatever third-party sales GSK may have made to SNHD is immaterial to the immunity to which Apexus is entitled as the underlying conduct of Apexus – the negotiation of pricing – is protected.

III. APEXUS CANNOT BE LIABLE FOR AIDING AND ABETTING

Plaintiff's sole cause of action as to Apexus is restricted to a hope that the independent acts of third parties might somehow taint the protected and otherwise immune activity of Apexus. However, such a hope fails to comport with the law, as no Court has recognized "aiding and abetting" civil violations of the U.S. antitrust laws, and specifically the Robinson-Patman Act, as a grounds for recovery.

Although Plaintiff propounds a litany of Apexus's purported misdeeds, Plaintiff's Amended Complaint (the "Complaint") (Dkt. #154) includes but a single legal cause of action against Apexus: "Aiding and Abetting Liability". See Complaint at ¶¶ 63-66. A cause of action for aiding and abetting civil violations of the U.S. antitrust laws, and specifically the Robinson-Patman Act does not exist under federal law. See e.g. MCI v. Graphnet, 881 F.Supp. 126 (D.N.J. 1995) (relying on the reasoning in Central Bank of Denver v. First Interst. Bank of Denver, 511 U.S. 164 (1994), the district court concluded that there was no civil aiding and abetting liability under Section 2 where there is no express language in the underlying statute, as Congress certainly knows how to "impose aiding and abetting liability when it [chooses] to do so.".); Gen. Supply Deck & Floor Underlayment v. Maxxon, 2001 WL 1480768 (N.D.Tex. Nov. 19, 2001) (granting defendants' motion for summary judgment and dismissing plaintiff's conspiracy to violate the Robinson-Patman Act claim because such a claim is not cognizable).

⁸ Just as a gun store is not an accomplice to every crime committed by a weapon purchaser who commits a crime with a lawfully purchased weapon, Apexus's lawful negotiation of prices as Prime Vendor does not render it a conspirator if the recipient of the negotiated price thereafter commits some tortious act.

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To the extent that Plaintiff rests its "aiding and abetting" theory on some state law cause of
action, Plaintiff's state law theory is similarly barred. Because the Nevada Unfair Trade Practices
Act adopts by reference the case law applicable to the federal antitrust laws, there can also be no
civil aiding and abetting liability stemming from that statute. Nev.Rev.Stat. § 598A.050 ("The
provisions of this chapter shall be construed in harmony with prevailing judicial interpretations of
the federal antitrust statutes."); See Boulware v. State of Nev., Dep't of Human Res., 960 F.2d 793,
800-01 (9th Cir. 1992) (finding Noerr-Pennington immunity barred both the federal antitrust claim
as well as the Nevada Unfair Trade Practices Act claim because "The Nevada statute also adopts by
reference the case law applicable to the federal antitrust laws."). Accordingly, Plaintiff's sole cause
of action fails, and Apexus's Summary Judgment should be granted.

WHEREFORE, Apexus requests this Court grant Apexus's Motion for Summary Judgment, and to award it any further relief, in either law or equity, to which it has shown itself entitled.

Dated this 3rd day of October, 2014.

Respectfully submitted,

/s/ Gregory J. Casas

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CERTIFICATE OF SERVICE

Pursuant to Fed. R. Civ. P. 5(b), I hereby certify that on October 3, 2014, service of the foregoing Reply to Plaintiff's Response to Apexus's Motion for Summary Judgment was made this date through the United States District Court's CM/ECF electronic filing system.

/s/ Joyce Heilich

An employee of Greenberg Traurig, LLP